The 35 U.S.C. §§ 102(e)/ 103(a) rejection of claims 34, 16, 18 and 19 over Peltola et al. is respectfully traversed. As discussed above, Peltola et al. is not a reference against this application. Reconsideration and withdrawal of the anticipation and alternative obviousness rejection of claims 34, 16, 18 and 19 over Peltola et al. are respectfully requested.

The 35 U.S.C. § 112, second paragraph, rejection of claims 34, 16, 18 and 19 is traversed. Claim 34 requires a correlation step ("correlating a desired biodegradability of a silica fiber with a viscosity of a silica sol") and that the fiber spinning process is begun when the viscosity of the silica gel reaches a value correlating to the desired biodegradability of the silica fiber. Thus, claim 34 does not read on simply "deciding to spin the fiber after the sol has reached a specific viscosity" (Official Action, page 12, lines 13-14). Instead, claim 34 expressly requires the spinning process to begin when the sol's viscosity reaches a value which corresponds (correlates) to the desired degree of biodegradability. The absence of a numerical viscosity value does not render the claim indefinite, or permit the Patent Office to ignore the express requirements of the claim.

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One of ordinary skill in the art would understand from the specification and figures that a desired biodegradability of the silica fiber is correlated with spinning the fiber when the sol viscosity reaches a certain value, and that silica fiber biodegradability is quantitatively expressed as weight percent silica dissolution in simulated body fluid (SBF)/hour. This is evident from Example 3, which evaluates silica fiber biodegradability in vitro as a function of silica solubility in SBF/wt-%/h. In short, silica solubility in SBF is a quantitative measure of biodegradability. Compare the description of Fig. 6 ("Fig. 6 shows the biodegradation of the green state fibers aged for three months...") with the actual Y axis property in the graph of Fig. 6 ("Solubility of silica/ wt%").

Whether the correlation step is recited in an independent claim or a dependent claim is immaterial to the issue of whether the claimed step is understandable to one of ordinary skill in the art.

Reconsideration and withdrawal of the indefiniteness rejection of claims 34, 16, 18 and 19 are earnestly requested.

The 35 U.S.C. § 112, first paragraph, rejection of claims 34, 16, 18 and 19 for failure to comply with the written description

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requirement is traversed. The application conveys to one of ordinary skill in the art that the inventors had possession of the claimed method and, in particular, the correlation step of claim 34 ("correlating a desired biodegradability of a silica fiber with a viscosity of a silica sol") at the time the application was filed. The specification explicitly states that fiber biodegradability can be adjusted for desired purposes by controlling the viscosity of the spinning solution for determining the starting point of the spinning (page 5, lines 6-10). The silica sol is spinnable within a certain time period, rather than at a single point, and the silica sol viscosity increases during this time period. In the earlier stage of spinnability the silica polymers are somewhat smaller and they are packed easier, forming denser structures than the larger silica polymers of the later stage of spinnability. Fibers spun in the earlier stage of the spinnability period degrade more slowly in simulated body fluid than fibers spun in the later stage of spinnability (Specification, page 5, lines 11-24 and page 16, lines 17-21). Example 3 illustrates silica fiber biodegradability as a function of the starting point of the spinning process, as quantitatively measured by silica solubility in SBF/wt-%/h.

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The drawings confirm the inventors had possession of the invention at the time the application was filed. Figure 5 shows the spinning viscosity as a function of the starting point of the spinning process for several fibers. Figures 8, 10 and 12 illustrate the SiO_2 solubility in wt-%/h in SBF as a function of sol viscosity at the starting point of the spinning process for various fibers at different aging time periods.

One of ordinary skill in the art would understand, from the application as originally filed, that (1) silica fiber biodegradability is quantitatively expressed as weight percent silica solubility in simulated body fluid/hour, (2) silica fibers which are spun when the sol has less viscosity (in the earlier stage of the spinnability period) will degrade more slowly in simulated body fluid than fibers spun from a sol having a higher viscosity, (3) a silica fiber having a desired degree of biodegradability can be produced by beginning the fiber spinning step at a spinning sol viscosity which correlates[1] to the desired

[1]Correlate - (1) To put or bring into casual, complementary, parallel, or reciprocal relation. (2) To establish or demonstrate as having a correlation. To be related by a correlation. Related by a correlation, esp. having corresponding characteristics. Either of two correlate entities. Webster's II New Riverside University Dictionary 314 (1984)

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degree of biodegradability, and (4) one way to determine the correlation between sol viscosity and a desired silica fiber biodegradability is to refer to graphs which correlate biodegradability (expressed as the fiber's SiO_2 solubility rate in weight %/hour) and the viscosity of the sol when fiber spinning began, such as those shown in Figs. 8, 10 and 12.[2]

Reconsideration and withdrawal of the 35 U.S.C. § 112, first paragraph, rejection of claims 34, 16, 18 and 19 are earnestly requested.

The 35 U.S.C. § 102(b) rejection of claims 34, 16, 18 and 19 over U.S. Patent No. 4,919,871 to Lin et al. is traversed. Method claim 34 includes a correlation step in which the desired biodegradability of a silica fiber is correlated with the viscosity of a silica sol at the time the fiber is spun. Spinning is begun when the silica sol's viscosity reaches a value correlating to the desired biodegradability of the silica fiber.

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[2]One of ordinary skill in the art would also understand another way to determine the correlation between a desired degree of silica fiber biodegradability and so viscosity would be to construct a table (as opposed to a graph) showing sol viscosity at initiation of fiber spinning and the resulting fiber's biodegradability.

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Lin et al. utterly fails to disclose, either expressly or inherently, the correlation and spinning steps expressly required by claim 34. Instead, the reference merely teaches permitting hydrolysis and condensation reactions to proceed until the sol has a suitable viscosity for fiber forming (Col. 2, line 67 to Col. 3, line 1). Ageing of the sol to a desired spinning viscosity does not disclose or suggest correlating the production of a silica fiber having a desired degree of biodegradability with the initiation of fiber spinning at a particular sol viscosity.

The Patent Office appears to argue that Lin et al. inherently discloses the claimed method by noting Example 12 of the reference "meets" a spinnability viscosity range of claims 16, 18 and 19. However, Example 12 of Lin et al. does not perform or suggest the correlation step of claim 34.

The Patent Office argument that there is no data in applicants' specification where viscosity is correlated with biodegradability is incorrect. As discussed above, a quantitative measure of a silica fiber's biodegradability is its rate of silica dissolution or solubility in simulated body fluid, expressed as weight percent/hour. The applicants' specification includes such

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data on several fibers (FIB1, FIB2 and FIB3). See Figs. 8, 10 and 12.

Yet another reason why Lin et al. does not anticipate the claimed method is that Lin et al. fails to disclose, either expressly or inherently, a method for production of a biodegradable fiber. One of ordinary skill in the art would understand a biodegradable silica fiber has numerous hydroxyl groups on the fiber surface. Without these hydroxyl groups the fiber would not be biodegradable. In contrast, Lin et al. teaches drying its silica fibers in an ammonia atmosphere to a non-sticky state. However, if the forming fiber is treated with ammonia the hydroxyl groups will be condensed to hydrophobic siloxane groups (Si-O-Si-) and at the same time the fiber's porosity will be reduced. In short, the basis of the silica fiber's biodegradability is effectively destroyed.

Reconsideration and withdrawal of the anticipation rejection of claims 34, 16, 18 and 19 over Lin et al. are earnestly requested.

The alternative obviousness rejection of claims 34, 16, 18 and 19 over Lin et al. is also traversed. As pointed out above, the claimed method requires the production of a biodegradable silica

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fiber by correlating the desired degree of biodegradability with starting fiber spinning at a particular sol-gel viscosity.

Lin et al. fails to raise a prima facie case of obviousness against the claimed method because this reference fails to disclose teach, or suggest the production of a biodegradable silica fiber by correlating the desired degree of biodegradability with starting fiber spinning at a particular sol viscosity. Merely ageing a sol to a "desired" spinning viscosity does not suggest or otherwise render obvious the step of beginning a fiber spinning process when the viscosity of the silica sol reaches a value correlating to a desired biodegradability of the resulting silica fiber.

Lin et al. is directed to an entirely different problem (fiber stickiness). One of ordinary skill in the art is given no motivation or suggestion to either (1) eliminate Lin et al.'s ammonia treatment to produce a biodegradable fiber, or (2) start its fiber spinning process at a particular viscosity in order to produce a fiber with a desired degree of biodegradability.

Reconsideration and withdrawal of the obviousness rejection of claims 34, 16, 18 and 19 over Lin et al. are earnestly requested.

The 35 U.S.C. § 102(b) rejection of claim 34 over PCT Patent Publication WO 97/45367 to Ahola et al. is respectfully traversed.

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Method claim 34 includes a correlation step in which the desired biodegradability of a silica fiber is correlated with the viscosity of a silica sol at the time the fiber is spun. In this regard, fiber can be spun from a silica sol within a certain time period rather than at a single point in time. The viscosity of the silica sol does not remain constant but rather increases during this time period. Spinning is begun when the silica sol's viscosity reaches a value correlating to the desired biodegradability of the silica fiber. See specification, page 5, lines 11-14.

Ahola et al. utterly fails to disclose the correlation step of claim 34 because this reference does not teach the initiation of a spinning step at a specific viscosity to produce a silica fiber having a desired degree of biodegradability. Merely deciding to initiate spinning of the sol at a specific viscosity does not perform or otherwise disclose a correlation step between desired biodegradability of the silica fiber and a specific viscosity. Reconsideration and withdrawal of the anticipation rejection of claim 34 over Ahola et al. are earnestly requested.

The alternative obviousness rejection of claims 34, 16, 18 and 19 over Ahola et al. is also traversed. A feature of the claimed method for preparing a biodegradable silica fiber is a correlation

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step in which the desired biodegradability of a silica fiber is correlated with the viscosity of a silica sol at the time the fiber is spun. Spinning is begun when the silica sol's viscosity reaches a value correlating to the desired biodegradability of the silica fiber.

Ahola et al. fails to raise a prima facie case of obviousness against the claimed method because the reference fails to disclose or suggest the correlation step of the claimed method. As noted above, Ahola et al.'s decision to initiate spinning of its sol at a specific viscosity does not perform, disclose, teach or suggest a correlation step between desired biodegradability of the silica fiber and a specific viscosity.

Ahola et al. discloses a controllably dissolvable silica xerogel prepared by a sol-gel process in which gelation of the sol and evaporation of the solvent occur simultaneously (Page 3, lines 25-33). One of ordinary skill in the art is given no motivation or suggestion to correlate the desired biodegradability of a silica fiber with the viscosity of a silica sol at the time the fiber is spun. Reconsideration and withdrawal of the obviousness rejection of claims 34, 16, 18 and 19 over Ahola et al. are earnestly requested.

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The 35 U.S.C. § 103(a) rejection of claims 24-33 over Ahola et al. is also traversed. A feature of claims 24-33 is a biodegradable silica fiber having a solubility in simulated body fluid of from 0.2 to 20 wt-%/h. The slowest (0.2 wt-%/hour minimum) solubility rate means that the fiber will completely dissolve in about 21 days.

Ahola et al. fails to raise a prima facie case of obviousness against the claims because this reference fails to disclose or suggest the biodegradable fiber feature of the claimed invention. As conceded by the Patent Office, Ahola et al. fails to disclose the 0.2 to 20 wt-%/hour silica solubility range feature of the claimed biodegradable fiber. Instead, the dessicated fiber of its Example 2 had a solubility rate of 10 wt-%/4 weeks, or 0.0148 wt-%/hour, which is approximately 20 times slower to dissolve than the claimed biodegradable fiber. The Ahola et al. fibers will require 40 weeks to dissolve completely.

Applicants have previously pointed out that silica fibers having the fast dissolution times of the claimed fiber simply had not been achieved before their invention. The slowly dissolving fibers of Ahola et al. and German '551 (which completely dissolve within 50-500 days) support their position. In stark contrast, the

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Patent Office has failed to cite *any* documentary evidence to demonstrate that selection of a silica dissolution rate, including a very fast silica dissolution rate, was merely a matter of design choice. If this rejection is maintained, the Examiner is requested to either supply documentary evidence demonstrating that the prior art could produce rapidly dissolving silica fibers, i.e., having a solubility of from 0.2 to 20 wt-%/hour, or to explain the facts within her personal knowledge which support this rejection, pursuant to 37 C.F.R. § 1.104(d)(2).

MPEP § 2112.01 is irrelevant to this rejection because there is no basis to assume the claimed fiber and the Ahola et al. silica fibers have a substantially identical chemical composition and fiber structure. Silica fiber biodegradability is affected by other factors in addition to the viscosity at which spinning is begun, including ageing and silica saturation level. See Table 3 and page 15, lines 19-21 of the specification. There is no basis for the Patent Office assumption that the Ahola et al. fiber is identical to the claimed biodegradable fiber because there is no evidence that the Ahola et al. fiber was made by the same method and subjected to the same conditions as the claimed biodegradable silica fiber.

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Reconsideration and withdrawal of the obviousness rejection of claims 24-33 over Ahola et al. are earnestly requested.

The 35 U.S.C. § 103(a) rejection of claims 16, 18, 19 and 24-34 over German patent DE 196 09 551 ("German '551") is respectfully traversed. The patentable features of method claims 34, 16, 18 and 19 are discussed separately from the patentable features of the fiber/delivery device/pharmaceutical composition and method of treatment claims 24-33.

1. Method Claims 34, 16, 18 and 19

A feature of the claimed method for preparing a biodegradable silica fiber is a correlation step in which the desired biodegradability of a silica fiber is correlated with the viscosity of a silica sol at the time the fiber is spun. Spinning is begun when the silica sol's viscosity reaches a value correlating to the desired biodegradability of the silica fiber.

German '551 fails to raise a prima facie case of obviousness against the claimed method because this reference does not disclose, teach or suggest the correlation step of the claimed method. Merely deciding to initiate spinning of the sol at a specific viscosity does not perform, disclose, teach or suggest a correlation step between desired biodegradability of the silica

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correlation step between desired biodegradability of the silica fiber and a specific sol viscosity.

German '551 explicitly teaches that silica fiber biodegradability can be controlled through silanol content (English translation, page 5, lines 21-26). One of ordinary skill in the art is given no suggestion or motivation to select a particular viscosity at which to begin spinning the fiber to achieve a desired fiber biodegradation rate. Reconsideration and withdrawal of the obviousness rejection of claims 34, 16, 18 and 19 over German '551 are earnestly requested.

2. Fiber/Delivery Device/Pharmaceutical Composition Claims 24-33

As previously discussed, a feature of claims 24-33 is a biodegradable silica fiber having a solubility in simulated body fluid of from 0.2 to 20 wt-%/h.

German '551 fails to raise a prima facie case of obviousness against the claimed fiber (and delivery device, pharmaceutical composition and method of treatment based thereon) because this reference fails to disclose or suggest the solubility range required by the claimed fiber (which will result in complete fiber dissolution in about 21 days for the lower (slower) dissolution

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range limit). In contrast, German '551 discloses a fiber whose *fastest* dissolution time is 50 days.

One of ordinary skill in the art would consider this difference in fiber dissolution times (21 days *vs.* 50 days) to be unexpected or surprising. Silica fibers with such fast dissolution times simply had not been achieved by the prior art, as demonstrated by both German '551 (dissolution times of 50 days or more) and Ahola et al. (dissolution time of 40 weeks). One or ordinary skill in the art simply would not have believed silica fibers with such a fast dissolution rate (0.2 to 20 wt-%/h) could be prepared.

Fibers with fast or very fast dissolution rates can be used for different applications. In tissue engineering and guiding applications it can be very important that the fiber dissolves rather quickly. In such applications support for cell growth is needed for a specific time only; after that limited time undissolved fiber can hinder the desired path of cell growth and thus be a hindrance. Fast dissolution rates are also advantageous in many delivery device applications in which a specific agent is delivered for a period of one or two weeks or even a shorter time period. In such devices the agent is delivered through dissolution

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of the fiber and thus dissolution time equal to the intended/desired delivery period is of utmost importance.

Reconsideration and withdrawal of the obviousness rejection of claims 24-33 over German '551 are earnestly requested.

It is believed this application is in condition for allowance. Reconsideration and withdrawal of all rejections of claims 16, 18, 19 and 24-34, and issuance of a Notice of Allowance directed to those claims, are earnestly requested. The Examiner is urged to telephone the undersigned should she believe any further action is required for allowance.

It is not believed any fee is required for entry and consideration of this Request. Nevertheless, the Commissioner is authorized to charge our Deposit Account No. 50-1258 in the amount of any such required fee.

Respectfully submitted,

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